Attachment 10

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 01/29/2018

Department of Health and Human Services
Food and Drug Administration

FOR CERTIFYING OFFICIAL: Beth Killoran
FOR CLEARANCE OFFICER: Darius Taylor

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 09/19/2017

ACTION REQUESTED: New collection (Request for a new OMB Control Number)
TYPE OF REVIEW REQUESTED: Regular
ICR REFERENCE NUMBER: 201708-0910-011
AGENCY ICR TRACKING NUMBER: CTP
TITLE: Experimental Study on Warning Statements for Cigarette Graphic Health Warnings
LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved with change
OMB CONTROL NUMBER: 0910-0848
The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 01/31/2021 DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	0	0	0
New	22,444	1,305	0
Difference			
Change due to New Statute	0	0	0
Change due to Agency Discretion	22,444	1,305	0
Change due to Agency Adjustment	0	0	0
Change due to PRA Violation	0	0	0

TERMS OF CLEARANCE: Approved consistent with the understanding that this study is not intended to generate nationally representative outcomes. Due to the study design, convenience sampling methodology, and methods of analyses-- significant limitations exist with regard to the generalizability of results from this study. Panelists are recruited into the online panel using convenience sampling methods, and thus do not have a known probability of selection into the panel. Recruitment of the study sample from the online panel is also subject to bias resulting from potential differences between survey responders (i.e., panelists who received the invitation and opted to participate in our study) and non-responders (i.e., panelists who were invited but chose not to participate) in characteristics that may be associated with key study outcomes. Because of these limitations, the relationship between treatment and outcomes we find in our study may not generalize to the broader U.S. population. FDA confirms that all such limitations inherent in the study design and methodology will be communicated in all reports, presentations, and policy documents.

OMB Authorizing Official: Dominic J. Mancini
Deputy and Acting Administrator,
Office Of Information And Regulatory Affairs

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Adult Screener			
Adult Pretest and Main data collection			
Adolescent Screener			
Adolescent Pretest & Main data collection			